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EXAMINER	
THANGAVELU, KANDASAMY	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/643,982	Applicant(s) ST. VILLE, JAMES A.	
	Examiner Kandasamy Thangavelu	Art Unit 2123	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 July 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-55* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-55* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *23 August 2000* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☒ The proposed drawing correction filed on *24 October 2002* is: a)☒ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Introduction

1. This communication is in response to the Applicants' Amendments dated July 29, 2003 and August 5, 2003. Claims 1, 4, 10-20, 22, 25, and 27-37 were amended. Claims 43-55 were added. Claims 21, 26 and 42 were further amended on August 5, 2003. Claims 1-55 of the application are pending in the application. This office action is made final.

Response to Arguments

2. Applicant's arguments filed on July 29, 2003 have been fully considered. The nonstatutory double patenting rejections of Claims 1, 25 and 41 are withdrawn in response to applicant's amendment to those claims. The arguments with respect to 103 (a) rejections of Claims 1, 25 and 41 are moot in view of the new ground(s) of rejection which are applied against the amended claims. The applicant's amendments necessitated the new grounds of rejection.

Domestic Priority not Granted

3. This application contains a claim for the benefit of priority based on U.S. Provisional Application No. 60/149,896 filed on August 23, 1999. Provisional Application 60/149,896 has

been reviewed and priority denied, because the Provisional Application 60/149,896 fails to satisfy the requirements of 35 U.S.C section 112, first paragraph, as described below:

The provisional application does not describe determining manufacturing parameters for controlling manufacturing equipment based on the matched material property coefficients;

controlling the manufacturing equipment in accordance with the determined manufacturing parameters to manufacture the object; and

introducing an impurity into the object while the object is manufactured.

These limitations are essential parts of the independent claims 1, 25, 41 and 46.

Drawings

4. The draft person has objected to the drawings; see a copy of Form PTO-948 for an explanation.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 1, 2, 4-10, 21-27, 38-42 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over **St. Ville (VI)** (U.S. Patent 5,594,651) in view of **Wu et al. (WU)** (U.S. Patent 5,654,077), and further in view of **Yamazaki (YA)** (U.S. Patent 6,197,624).

6.1 **VI** teaches a method and apparatus for manufacturing a prosthesis having optimized response characteristics. Specifically, as per Claim 1, **VI** teaches a method for manufacturing an object having a potential { x } that is generated in response to a field { f } applied (Col 4, Lines 43-45 and Col 6, Lines 44-53); the method comprising the steps of:

generating a computerized mathematical model of the object by discretizing a geometric model of the object into a plurality of finite elements (Col 4, Lines 46-49); and

specifying values for the field { f } and potential { x } relative to the finite elements (Col 4, Lines 50-51);

extracting material property coefficients from the material property matrix [k] for each finite element in the computerized mathematical model (Col 4, Lines 53-55);

comparing the extracted material property coefficients to material property coefficients for known materials to match the extracted material property coefficients to the material property coefficients for known materials (Col 4, Lines 55-59);

determining manufacturing parameters for controlling manufacturing equipment for each volume increment of the object based on the matched material property coefficients (Col 4, Lines 59-61; Col 11, Lines 35-38; Col 13, Line 1-8; Lines 21-23); and

controlling the manufacturing equipment in accordance with the determined manufacturing parameters to thereby manufacture the object (Col 4, Lines 61-62; Col 12, Lines 13-18; Col 14, Lines 44-48).

VI teaches that the method includes specifying the material properties of the finite elements (Col 4, Lines 51-52). **VI** does not expressly teach that the method includes specifying that the material properties of the finite elements have a particular symmetry. **WU** teaches that the method includes specifying that the material properties of the finite elements have a particular symmetry (Col 1, Lines 65-67 and Col 5, Lines 26-33), as both **VI** and **WU** deal with material properties of multimaterial laminate, and the symmetry eliminates weak spots in the structural element and provides maximum weight reduction in a structural component (Col 5, Lines 22-24 and 27-28). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **VI** with the method of **WU** specifying that the material properties of the finite elements have a particular symmetry, as both **VI** and **WU** deal with material properties of multimaterial laminate, and the symmetry would eliminate weak spots in the structural element and provide maximum weight reduction in a structural component.

VI teaches that the method includes calculating a material property matrix [k] based on the relationship { f }=[k] { x } (Col 4, Lines 51-52). **VI** does not expressly teach that the method includes calculating a material property matrix [k] based on the relationship { f }=[k] { x } and the specified symmetry. **WU** teaches that the method includes calculating a material property matrix [k] based on the specified symmetry (Col 1, Lines 65-67 and Col 5, Lines 26-33), as both **VI** and **WU** deal with material properties of multimaterial laminate, and the symmetry eliminates weak spots in the structural element and provides maximum weight reduction in a structural component (Col 5, Lines 22-24 and 27-28). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **VI** with the method of **WU** that included calculating a material property matrix [k] based on the specified symmetry, as both **VI** and **WU** deal with material properties of multimaterial laminate, and the symmetry would eliminate weak spots in the structural element and provide maximum weight reduction in a structural component.

VI teaches determining variables for the respective volume increments of the object (Col 13, Lines 1-8 and 21-23). **VI** does not expressly teach introducing an impurity into the object while the object is manufactured, wherein an amount of the introduced impurity is variable for the respective volume increments of the object. **YA** teaches introducing an impurity into the object while the object is manufactured, wherein an amount of the introduced impurity is variable for the respective volume increments of the object (Col 2, Lines 35-46; Col 2, Lines 15-33), as introducing impurity into the object provides a technique of obtaining desired material properties by doping the material with an impurity of proper concentration (Col 1, Lines 65-67 and 38-40). It would have been obvious to one of ordinary skill in the art at the time of

Applicant's invention to modify the method of **VI** with the method of **YA** that included introducing an impurity into the object while the object is manufactured, wherein an amount of the introduced impurity is variable for the respective volume increments of the object, as introducing impurity into the object would provide a technique of obtaining desired material properties by doping the material with an impurity of proper concentration.

6.2 As per Claim 2, **VI, WU** and **YA** teach the method of Claim 1. **VI** does not expressly teach that the material properties of the finite elements are specified to be isotropic. **WU** teaches that the material properties of the finite elements are specified to be isotropic (Col 5, Lines 26-33), as that eliminates weak spots in the structural element and provides maximum weight reduction in a structural component (Col 5, Lines 22-24 and 27-28). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **VI** with the method of **WU**, as that would eliminate weak spots in the structural element and provide maximum weight reduction in a structural component.

6.3 As per Claim 4, **VI, WU** and **YA** teach the method of Claim 1. **VI** also teaches generating of a computerized mathematical model of the object includes determining the smallest volume increment that can be manufactured using the manufacturing equipment. (Col 13, Lines 1-8 and Col 13, Lines 21-23).

6.4 As per Claim 5, **VI, WU** and **YA** teach the method of Claim 1. **VI** also teaches that the field { f } is a mechanical force field and the potential { x } is a displacement. (Col 7, Lines 53-67).

6.5 As per Claim 6, **VI, WU** and **YA** teach the method of Claim 1. **VI** also teaches that the field {f} is an electric current field and the potential { x } is a voltage. (Col 7, Lines 53-67).

6.6 As per Claim 7, **VI, WU** and **YA** teach the method of Claim 1. **VI** also teaches that the field {f} is a magnetic field and the potential { x } is a magnetic vector potential. (Col 7, Lines 53-67).

6.7 As per Claim 8, **VI, WU** and **YA** teach the method of Claim 1. **VI** also teaches that the field {f} is a thermal flux field and the potential { x } is a temperature. (Col 7, Lines 53-67).

6.8 As per Claim 9, **VI, WU** and **YA** teach the method of Claim 1. **VI** also teaches that the field { f } is a fluid velocity field and the potential {x} is a fluid potential. (Col 7, Lines 53-67).

6.9 As per Claim 10, **VI, WU** and **YA** teach the method of Claim 1. **VI** also teaches that controlling of the manufacturing equipment comprises controlling a composite manufacturing equipment for manufacturing a composite material. (Col 12, Lines 13-18 and Col 12, Lines 23-29).

6.10 As per Claim 21, **VI, WU** and **YA** teach the method of Claim 1. **VI** also teaches that the object being manufactured is a prosthetic implant for replacing a body part and the field {f} and potential {x} are specified based on the in vivo forces applied to the body part to be replaced and the in vivo displacements generated in the body part to be replaced when the forces are applied (Col 8, Lines 23-35 and Col 8, Lines 39-44).

6.11 As per Claim 22, **VI, WU** and **YA** teach the method of Claim 1. **VI** teaches an object made in accordance with the method of claim 1 (Col 6, Lines 58-62);

the object is selected from the group consisting of an automobile part, an aircraft part, a prosthetic implant, a golf club shaft, a tennis racket, a bicycle frame, and a fishing pole (Col 6, Lines 58-62); and

different portions of the object have different material properties corresponding to the matched extracted material property coefficients for known materials (Col 4, Lines 46-59).

6.12 As per Claim 23, **VI, WU** and **YA** teach the method of Claim 1. **VI** teaches a prosthetic implant manufactured in accordance with the method of claim 1 (Col 8, Lines 23-35 and Col 8, Lines 39-44).

6.13 As per Claim 24, **VI, WU** and **YA** teach the method of Claim 1. **VI** teaches a golf club manufactured in accordance with the method of claim 1. (Col 6, Lines 58-62).

6.14 As per Claim 25, **VI** teaches a computer-implemented method for determining machine control instructions for manufacturing an object having a potential { x } that is generated in response to a field {f} applied (Col 14, Lines 44-48 and Col 6, Lines 44-53); the method comprising the steps of:

generating a computerized mathematical model of the object by discretizing a geometric model of the object into a plurality of finite elements (Col 4, Lines 46-49);

specifying values for the field { f } and potential { x } relative to the finite elements (Col 4, Lines 50-51);

extracting material property coefficients from the material property matrix [k] for each finite element in the computerized mathematical model (Col 4, Lines 53-55);

comparing the extracted material property coefficients to material property coefficients for known materials to match the extracted material property coefficients to the material property coefficients for known materials (Col 4, Lines 55-59);

determining manufacturing parameters for controlling manufacturing equipment for each volume increment of the object based on the matched material property coefficients (Col 4, Lines 59-61; Col 11, Lines 35-38; Col 13, Line 1-8; Lines 21-23); and

generating machine control instructions for controlling the manufacturing equipment in accordance with the manufacturing parameters (Col 14, Lines 44-48).

VI does not expressly teach that the method includes specifying that the material properties of the finite elements have a particular symmetry. **WU** teaches that the method includes specifying that the material properties of the finite elements have a particular symmetry (Col 1, Lines 65-67 and Col 5, Lines 26-33), as that eliminates weak spots in the structural

element and provides maximum weight reduction in a structural component (Col 5, Lines 22-24 and 27-28). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **VI** with the method of **WU** specifying that the material properties of the finite elements have a particular symmetry, as that would eliminate weak spots in the structural element and provide maximum weight reduction in a structural component.

VI teaches that the method includes calculating a material property matrix [k] based on the relationship { f }=[k] { x } (Col 4, Lines 51-52). **VI** does not expressly teach that the method includes calculating a material property matrix [k] based on the relationship { f }=[k] { x } and the specified symmetry. **WU** teaches that the method includes calculating a material property matrix [k] based on the specified symmetry (Col 1, Lines 65-67 and Col 5, Lines 26-33), as that eliminates weak spots in the structural element and provides maximum weight reduction in a structural component (Col 5, Lines 22-24 and 27-28). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **VI** with the method of **WU** that included calculating a material property matrix [k] based on the specified symmetry, as that would eliminate weak spots in the structural element and provide maximum weight reduction in a structural component.

VI teaches generating machine control instructions for controlling the manufacturing equipment (Col 14, Lines 44-48). **VI** teaches determining variables for the respective volume increments of the object (Col 13, Lines 1-8 and 21-23). **VI** does not expressly teach introducing an impurity into the object while the object is manufactured, wherein an amount of the introduced impurity is variable for the respective volume increments of the object. **YA** teaches

introducing an impurity into the object while the object is manufactured, wherein an amount of the introduced impurity is variable for the respective volume increments of the object (Col 2, Lines 35-46; Col 2, Lines 15-33), as introducing impurity into the object provides a technique of obtaining desired material properties by doping the material with an impurity of proper concentration (Col 1, Lines 65-67 and 38-40). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **VI** with the method of **YA** that included introducing an impurity into the object while the object is manufactured, wherein an amount of the introduced impurity is variable for the respective volume increments of the object, as introducing impurity into the object would provide a technique of obtaining desired material properties by doping the material with an impurity of proper concentration.

6.15 As per Claim 26, **VI, WU** and **YA** teach the method of Claim 25. **VI** also teaches that the object being manufactured is a prosthetic implant for replacing a body part and the field {f} and potential {x} are specified based on the in vivo forces applied to the body part to be replaced and the in vivo displacements generated in the body part to be replaced when the forces are applied (Col 8, Lines 23-35 and Col 8, Lines 39-44).

6.16 As per Claim 27, **VI, WU** and **YA** teach the method of Claim 25. **VI** also teaches that the step of generating machine control instructions comprises generating machine control instructions for controlling composite manufacturing equipment for manufacturing a composite material. (Col 14, Lines 44-48 and Col 12, Lines 23-29).

6.17 As per Claim 38, **VI, WU** and **YA** teach the method of Claim 25. **VI** also teaches a computer system programmed to perform the method of claim 25. (Col 13, Line 53 to Col 14, Line 58 and Col 14, Lines 59-61).

6.18 As per Claim 39, **VI, WU** and **YA** teach the method of Claim 25. **VI** also teaches a control system programmed with machine control instructions for controlling composite manufacturing equipment to manufacture a composite object, where the machine control instructions are generated in accordance with the method of claim 25. (Col 12, Lines 23-25 and Col 12, Lines 39-42).

6.19 As per Claim 40, **VI, WU** and **YA** teach the method of Claim 25. **VI** also teaches composite manufacturing equipment comprising a control system programmed with machine control instructions for controlling the composite manufacturing equipment to manufacture a composite object, where the machine control instructions are generated in accordance with the method of claim 25. (Fig. 10; Col 12, Lines 39-42 and Col 15, Lines 28-42).

6.20 As per Claim 41, **VI** teaches a method for manufacturing an object for which a defined field { f } generates a potential {x} in response (Col 14, Lines 44-48 and Col 6, Lines 44-53); the method comprising the steps of:

generating a computerized mathematical model of the object by discretizing a geometric model of the object into a plurality of finite elements (Col 4, Lines 46-49);

specifying values of the field { f } and potential { x } relative to the finite elements (Col 4, Lines 50-51);

wherein the material property matrix [k] comprises a plurality of values each corresponding to one or more material property coefficients (Col 4, Lines 53-59);

comparing each of the plurality of values in the material property matrix [k] to known material properties (Col 4, Lines 55-59);

responsive to a match, selecting a corresponding manufacturing process parameter for a volume increment of the object, wherein the selected manufacturing process parameter is usable for controlling composite manufacturing equipment if the matched known material property is a material property for a composite material (Col 4, Lines 59-61 and Col 12, Lines 23-25; Col 13, Line 1-8; Lines 21-23); and

controlling the composite manufacturing equipment in accordance with the selected manufacturing process parameters to thereby manufacture the object (Col 14, Lines 44-48).

VI does not expressly teach that the method includes specifying that the material properties of the finite elements have a particular symmetry. **WU** teaches that the method includes specifying that the material properties of the finite elements have a particular symmetry (Col 1, Lines 65-67 and Col 5, Lines 26-33), as that eliminates weak spots in the structural element and provides maximum weight reduction in a structural component (Col 5, Lines 22-24 and 27-28). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **VI** with the method of **WU** specifying that the material properties of the finite elements have a particular symmetry, as that would eliminate

weak spots in the structural element and provide maximum weight reduction in a structural component.

VI teaches that the method includes calculating a material property matrix [k] based on the relationship { f }=[k] { x }(Col 4, Lines 51-52). **VI** does not expressly teach that the method includes calculating a material property matrix [k] based on the relationship { f }=[k] { x }and the specified symmetry. **WU** teaches that the method includes calculating a material property matrix [k] based on the specified symmetry (Col 1, Lines 65-67 and Col 5, Lines 26-33), as that eliminates weak spots in the structural element and provides maximum weight reduction in a structural component (Col 5, Lines 22-24 and 27-28). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **VI** with the method of **WU** that included calculating a material property matrix [k] based on the specified symmetry, as that would eliminate weak spots in the structural element and provide maximum weight reduction in a structural component.

VI teaches determining variables for the respective volume increments of the object (Col 13, Lines 1-8 and 21-23). **VI** does not expressly teach introducing an impurity into the object while the object is manufactured, wherein an amount of the introduced impurity is variable for the respective volume increments of the object. **YA** teaches introducing an impurity into the object while the object is manufactured, wherein an amount of the introduced impurity is variable for the respective volume increments of the object (Col 2, Lines 35-46; Col 2, Lines 15-33), as introducing impurity into the object provides a technique of obtaining desired material properties by doping the material with an impurity of proper concentration (Col 1, Lines 65-67 and 38-40). It would have been obvious to one of ordinary skill in the art at the time of

Applicant's invention to modify the method of **VI** with the method of **YA** that included introducing an impurity into the object while the object is manufactured, wherein an amount of the introduced impurity is variable for the respective volume increments of the object, as introducing impurity into the object would provide a technique of obtaining desired material properties by doping the material with an impurity of proper concentration.

6.21 As per Claim 42, **VI, WU** and **YA** teach the method of Claim 41. **VI** also teaches that the object being manufactured is a prosthetic implant for replacing a body part and the field {f} and potential {x} are specified based on the in vivo forces applied to the body part to be replaced and the in vivo displacements generated in the body part to be replaced when the forces are applied (Col 8, Lines 23-35 and Col 8, Lines 39-44).

6.22 As per Claim 46, **VI** teaches a method for manufacturing an object for which a defined field { f } generates a potential {x} in response (Col 14, Lines 44-48 and Col 6, Lines 44-53); the method comprising the steps of:

generating a computerized mathematical model of the object by discretizing a geometric model of the object into a plurality of finite elements (Col 4, Lines 46-49);

specifying values of the field { f } and potential { x } relative to the finite elements (Col 4, Lines 50-51);

calculating a material property matrix [k] based on the relationship { f }=[k] { x } (Col 4, Lines 51-52);

extracting material property coefficients from the material property matrix [k] for each finite element in the computerized mathematical model (Col 4, Lines 53-55);

comparing the extracted material property coefficients to material property coefficients for known materials to match the extracted material property coefficients to the material property coefficients for known materials (Col 4, Lines 55-59);

determining, based on the matched material property coefficients, manufacturing parameters for controlling manufacturing equipment for volume increments of the object corresponding to the finite elements of the geometrical model of the object (Col 4, Lines 59-61; Col 11, Lines 35-38; Col 13, Line 1-8; Lines 21-23; Col 4, Lines 46-49); and

controlling the manufacturing equipment in accordance with the determined manufacturing parameters to thereby manufacture the object (Col 4, Lines 61-62; Col 12, Lines 13-18; Col 14, Lines 44-48).

VI teaches determining variables by the manufacturing equipment from any one volume increment to another (Col 13, Lines 1-8 and 21-23). **VI** does not expressly teach introducing an impurity into the object while the object is manufactured, wherein an amount of the introduced impurity is controllably variable by the manufacturing equipment from any one volume increment to another. **YA** teaches introducing an impurity into the object while the object is manufactured, wherein an amount of the introduced impurity is controllably variable by the manufacturing equipment from any one volume increment to another (Col 2, Lines 35-46; Col 2, Lines 15-33), as introducing impurity into the object provides a technique of obtaining desired material properties by doping the material with an impurity of proper concentration (Col 1, Lines 65-67 and 38-40). It would have been obvious to one of ordinary skill in the art at the time of

Applicant's invention to modify the method of **VI** with the method of **YA** that included introducing an impurity into the object while the object is manufactured, wherein an amount of the introduced impurity is controllably variable by the manufacturing equipment from any one volume increment to another, as introducing impurity into the object would provide a technique of obtaining desired material properties by doping the material with an impurity of proper concentration.

7. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over **St. Ville (VI)** (U.S. Patent 5,594,651) in view of **Wu et al. (WU)** (U.S. Patent 5,654,077), and further in view of **Yamazaki (YA)** (U.S. Patent 6,197,624) and **Legere (LE)** (U.S. Patent 6,087,571).

7.1 As per Claim 3, **VI, WU** and **YA** teach the method of Claim 1. **VI, WU** and **YA** do not expressly teach that the material properties of the finite elements are specified to be transversely isotropic. **LE** teaches that the material properties of the finite elements are specified to be transversely isotropic (Col 6, Lines 55-65), so the material will have enhanced properties in the draw direction and properties similar to those of the undrawn polymer in all directions transverse to the draw direction (Col 6, Lines 53-55). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **VI, WU** and **YA** with method of **LE** that specifies that the material properties of the finite elements be transversely isotropic, so the material would have enhanced properties in the draw direction and properties similar to those of the undrawn polymer in all directions transverse to the draw direction.

8. Claims 11 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over **St. Ville (VI)** (U.S. Patent 5,594,651) in view of **Wu et al. (WU)** (U.S. Patent 5,654,077), and further in view of **Yamazaki (YA)** (U.S. Patent 6,197,624) and **Castanie et al (CA)** (U.S. Patent 6,290,889).

8.1 As per Claim 11, **VI, WU** and **YA** teach the method of Claim 10. **VI** does not expressly teach that the composite material comprises structural fibers laminated in a matrix and the impurity is introduced into the matrix. **WU** teaches the composite material comprises structural fibers laminated in a matrix (Col 1, Lines 15-20; Col 9, Lines 42-43). As per **CA** (Col 1, Lines 11-13), this facilitates producing an article having high strength, accuracy and temperature resistance characteristics. It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **VI** with method of **WU** that specifies that the composite material comprises structural fibers laminated in a matrix, since as per CA that would facilitate producing an article having high strength, accuracy and temperature resistance characteristics.

VI and **WU** do not expressly teach that the impurity is introduced into the matrix. **YA** teaches that the impurity is introduced into the matrix (Col 2, Lines 35-46; Col 2, Lines 15-33), as introducing impurity into the object provides a technique of obtaining desired material properties by doping the material with an impurity of proper concentration (Col 1, Lines 65-67 and 38-40). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **VI** and **WU** with the method of **YA** that included introducing an impurity into the matrix, as introducing impurity into the object would provide a

technique of obtaining desired material properties by doping the material with an impurity of proper concentration.

8.2 As per Claim 28, it is rejected based on the same reasoning as Claim 11, supra. Claim 28 is a method claim reciting the same limitation as Claim 11, as taught throughout by **VI, WU, YA** and **CA.**

9. Claims 12, 29 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over **St. Ville (VI)** (U.S. Patent 5,594,651) in view of **Wu et al. (WU)** (U.S. Patent 5,654,077), **Yamazaki (YA)** (U.S. Patent 6,197,624) and **Castanie et al. (CA)** (U.S. Patent 6,290,889), and further in view of **Abatangelo et al. (AB)** (WO 97/18842).

9.1 As per Claim 12, **VI, WU, YA** and **CA** teach the method of Claim 11. **VI, WU, YA** and **CA** do not expressly teach that the impurity comprises biologic material. **AB** teaches that the impurity comprises biologic material (Page 3, Para 4), since it is possible to seed and grow fibroblasts enabling production of an extracellular matrix similar to that of natural connective tissue (Page 2, Para 4). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **VI, WU, YA** and **CA** with method of **AB** that specifies that the impurity comprising biologic material, since it would be possible to seed and grow fibroblasts enabling production of an extracellular matrix similar to that of natural connective tissue.

9.2 As per Claims 29 and 47, these are rejected based on the same reasoning as Claim 12, supra. Claims 29 and 47 are method claims reciting the same limitation as Claim 12, as taught throughout by **VI, WU, YA, CA** and **AB.**

10. Claims 13, 30 and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over **St. Ville (VI)** (U.S. Patent 5,594,651) in view of **Wu et al. (WU)** (U.S. Patent 5,654,077), **Yamazaki (YA)** (U.S. Patent 6,197,624) and **Castanie et al. (CA)** (U.S. Patent 6,290,889), and further in view of **Johnson et al. (JO)** (U.S. Patent 6,296,667).

10.1 As per Claim 13, **VI, WU, YA** and **CA** teach the method of Claim 11. **VI, WU, YA** and **CA** do not expressly teach that the impurity comprises bone. **JO** teaches that the impurity comprises bone (Col 6, Lines 13-25), since that provides an osteoconductive matrix providing a scaffold for bone ingrowth and osteoinductive factors providing chemical agents that induce bone regeneration and repair (Col 1, Lines 27-30) It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **VI, WU, YA** and **CA** with method of **JO** that specified that the impurity comprised bone, since that would provide an osteoconductive matrix providing a scaffold for bone ingrowth and osteoinductive factors providing chemical agents that induce bone regeneration and repair.

10.2 As per Claims 30 and 48, these are rejected based on the same reasoning as Claim 13, supra. Claims 30 and 48 are method claims reciting the same limitation as Claim 13, as taught throughout by **VI, WU, YA, CA** and **JO.**

11. Claims 14, 31 and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over **St. Ville (VI)** (U.S. Patent 5,594,651) in view of **Wu et al. (WU)** (U.S. Patent 5,654,077), **Yamazaki (YA)** (U.S. Patent 6,197,624) and **Castanie et al. (CA)** (U.S. Patent 6,290,889), and further in view of **Bonadio et al. (BO)** (U.S. Patent 5,942,496).

11.1 As per Claim 14, **VI, WU, YA** and **CA** teach the method of Claim 11. **VI, WU, YA** and **CA** do not expressly teach that the impurity comprises crushed bone. **BO** teaches that the impurity comprises crushed bone (Col 58, Lines 29-34), since this material has the ability to simulate new bone formation (Col 58, Lines 35-36). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **VI, WU, YA** and **CA** with method of **BO** that specified that the impurity comprised crushed bone, since this material has the ability to simulate new bone formation.

11.2 As per Claims 31 and 49, these are rejected based on the same reasoning as Claim 14, supra. Claims 31 and 49 are method claims reciting the same limitation as Claim 14, as taught throughout by **VI, WU, YA, CA** and **BO.**

12. Claims 15, 32 and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over **St. Ville (VI)** (U.S. Patent 5,594,651) in view of **Wu et al. (WU)** (U.S. Patent 5,654,077), **Yamazaki (YA)** (U.S. Patent 6,197,624) and **Castanie et al. (CA)** (U.S. Patent 6,290,889), further in view of **Warren, Jr. (WA)** (U.S. Patent 6,348,042).

12.1 As per Claim 15, **VI, WU, YA** and **CA** teach the method of Claim 11. **VI, WU, YA** and **CA** do not expressly teach that the impurity comprises co-factors. **WA** teaches that the impurity comprises co-factors (abstract; Col 2, Lines 38-52), as the cofactors activate the enzyme impregnated in the lumen, within the biological system (Col 3, Lines 10-12). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **VI, WU, YA** and **CA** with method of **WA** that specified that the impurity comprised co-factors, as the cofactors activate the enzyme impregnated in the lumen, within the biological system.

12.2 As per Claims 32 and 50, these are rejected based on the same reasoning as Claim 15, supra. Claims 32 and 50 are method claims reciting the same limitation as Claim 15, as taught throughout by **VI, WU, YA, CA** and **WA.**

13. Claims 16, 33 and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over **St. Ville (VI)** (U.S. Patent 5,594,651) in view of **Wu et al. (WU)** (U.S. Patent 5,654,077), **Yamazaki (YA)** (U.S. Patent 6,197,624) and **Castanie et al. (CA)** (U.S. Patent 6,290,889), further in view of **Tadros et al. (TA)** (U.S. Patent 6,121,033).

13.1 As per Claim 16, **VI, WU, YA** and **CA** teach the method of Claim 11. **VI, WU, YA** and **CA** do not expressly teach that the impurity comprises biological cells. **TA** teaches that the impurity comprises biological cells (Col 14, Lines 39-52), as biological cells are completely

degradable into biomass without having toxic effect on the microbes (Col 14, Lines 41-43). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **VI, WU, YA** and **CA** with method of **TA** that specified that the impurity comprised biological cells, as biological cells are completely degradable into biomass without having toxic effect on the microbes.

13.2 As per Claims 33 and 51, these are rejected based on the same reasoning as Claim 16, supra. Claims 33 and 51 are method claims reciting the same limitation as Claim 16, as taught throughout by **VI, WU, YA, CA** and **TA.**

14. Claims 17, 34 and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over **St. Ville (VI)** (U.S. Patent 5,594,651) in view of **Wu et al. (WU)** (U.S. Patent 5,654,077), **Yamazaki (YA)** (U.S. Patent 6,197,624) and **Castanie et al. (CA)** (U.S. Patent 6,290,889), further in view of **Slaikeu (SL)** (U.S. Patent 6,231,590).

14.1 As per Claim 17, **VI, WU, YA** and **CA** teach the method of Claim 11. **VI, WU, YA** and **CA** do not expressly teach that the impurity comprises bio-active materials. **SL** teaches that the impurity comprises bio-active materials (Col 7, Lines 15-21), since such materials have properties to reduce friction, provide a therapeutic for local or blood borne delivery and enhance thrombosis, coagulation or platelet activity (Col 7, Lines 8-11). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **VI, WU, YA** and **CA** with method of **SL** that specified that the impurity comprised bio-active

materials, since that would describe the manufacturing method for materials including bio-active materials which would be useful to reducing friction, providing a therapeutic for local or blood delivery etc.

14.2 As per Claims 34 and 52, these are rejected based on the same reasoning as Claim 17, supra. Claims 34 and 52 are method claims reciting the same limitation as Claim 17, as taught throughout by **VI, WU, YA, CA** and **SL.**

15. Claims 18, 35 and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over **St. Ville (VI)** (U.S. Patent 5,594,651) in view of **Wu et al. (WU)** (U.S. Patent 5,654,077), **Yamazaki (YA)** (U.S. Patent 6,197,624) and **Castanie et al. (CA)** (U.S. Patent 6,290,889), further in view of **Hermann (HE)** (U.S. Patent 5,098,621).

15.1 As per Claim 18, **VI, WU, YA** and **CA** teach the method of Claim 11. **VI, WU, YA** and **CA** do not expressly teach that the impurity comprises medications. **HE** teaches that the impurity comprises medications (Col 9, Lines 49-55), as medications could be dispensed for the dressings (Col 9, Lines 51-52). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **VI, WU, YA** and **CA** with method of **HE** that specified that the impurity comprised medications, since medications could be dispensed for the dressings.

15.2 As per Claims 35 and 53, these are rejected based on the same reasoning as Claim 18, supra. Claims 35 and 53 are method claims reciting the same limitation as Claim 18, as taught throughout by **VI, WU, YA, CA** and **HE.**

16. Claims 19, 36 and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over **St. Ville (VI)** (U.S. Patent 5,594,651) in view of **Wu et al. (WU)** (U.S. Patent 5,654,077), **Yamazaki (YA)** (U.S. Patent 6,197,624) and **Castanie et al. (CA)** (U.S. Patent 6,290,889), further in view of **Phipps et al. (PH)** (U.S. Patent 6,289,242).

16.1 As per Claim 19, **VI, WU, YA** and **CA** teach the method of Claim 11. **VI, WU, YA** and **CA** do not expressly teach that the impurity comprises antibiotics. **PH** teaches that the impurity comprises antibiotics (Col 16, Lines 46-50), since antibiotics could be introduced into the host for use as anti-infectives (Col 16, Lines 46-50). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **VI, WU, YA** and **CA** with method of **PH** that specified that the impurity comprised antibiotics, since antibiotics could be introduced into the host for use as anti-infectives.

16.2 As per Claims 36 and 54, these are rejected based on the same reasoning as Claim 19, supra. Claims 36 and 54 are method claims reciting the same limitation as Claim 19, as taught throughout by **VI, WU, YA, CA** and **PH.**

17. Claims 20, 37 and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over **St. Ville (VI)** (U.S. Patent 5,594,651) in view of **Wu et al. (WU)** (U.S. Patent 5,654,077), **Yamazaki (YA)** (U.S. Patent 6,197,624) and **Castanie et al. (CA)** (U.S. Patent 6,290,889), further in view of **Mavity et al. (MA)** (U.S. Patent 6,248,057).

17.1 As per Claim 20, **VI, WU, YA** and **CA** teach the method of Claim 11. **VI, WU, YA** and **CA** do not expressly teach that the impurity comprises radioactive materials. **MA** teaches that the impurity comprises radioactive materials (Col 2, Lines 1-5), since they are useful for a variety of medical purposes, being particularly suitable for treatment of cancer (Abstract). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **VI, WU, YA** and **CA** with method of **MA** that specified that the impurity comprised radioactive materials, since they are useful for a variety of medical purposes, being particularly suitable for treatment of cancer.

17.2 As per Claims 37 and 55, these are rejected based on the same reasoning as Claim 20, supra. Claims 37 and 55 are method claims reciting the same limitation as Claim 20, as taught throughout by **VI, WU, YA, CA** and **MA.**

18. Claims 43-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over **St. Ville (VI)** (U.S. Patent 5,594,651) in view of **Wu et al. (WU)** (U.S. Patent 5,654,077), and **Yamazaki (YA)** (U.S. Patent 6,197,624), and further in view of **Abatangelo et al. (AB)** (WO 97/18842), **Johnson et al. (JO)** (U.S. Patent 6,296,667), **Bonadio et al. (BO)** (U.S. Patent 5,942,496),

Warren, Jr. (WA) (U.S. Patent 6,348,042), **Tadros et al. (TA)** (U.S. Patent 6,121,033), **Slaikeu (SL)** (U.S. Patent 6,231,590), **Hermann (HE)** (U.S. Patent 5,098,621), **Phipps et al. (PH)** (U.S. Patent 6,289,242), **Mavity et al. (MA)** (U.S. Patent 6,248,057).

18.1 As per Claim 43, **VI, WU** and **YA** teach the method of Claim 1. **VI, WU** and **YA** do not expressly teach that the impurity is selected from the group consisting of: biologic materials, bone, crushed bone, co-factors, biological cells, bio-active material, medications, antibiotics, and radioactive materials.

AB teaches that the impurity is selected from biologic material (Page 3, Para 4), since it is possible to seed and grow fibroblasts enabling production of an extracellular matrix similar to that of natural connective tissue (Page 2, Para 4). **JO** teaches that the impurity is selected from bone (Col 6, Lines 13-25), since that provides an osteoconductive matrix providing a scaffold for bone ingrowth and osteoinductive factors providing chemical agents that induce bone regeneration and repair (Col 1, Lines 27-30). **BO** teaches that the impurity is selected from crushed bone (Col 58, Lines 29-34), since this material has the ability to simulate new bone formation (Col 58, Lines 35-36). **WA** teaches that the impurity is selected from co-factors (abstract; Col 2, Lines 38-52), as the cofactors activate the enzyme impregnated in the lumen, within the biological system (Col 3, Lines 10-12). **TA** teaches that the impurity is selected from biological cells (Col 14, Lines 39-52), as biological cells are completely degradable into biomass without having toxic effect on the microbes (Col 14, Lines 41-43). **SL** teaches that the impurity is selected from bio-active materials (Col 7, Lines 15-21), since such materials have properties to reduce friction, provide a therapeutic for local or blood borne delivery and enhance thrombosis,

coagulation or platelet activity (Col 7, Lines 8-11). **HE** teaches that the impurity is selected from medications (Col 9, Lines 49-55), as medications could be dispensed for the dressings (Col 9, Lines 51-52). **PH** teaches that the impurity is selected from antibiotics (Col 16, Lines 46-50), since antibiotics could be introduced into the host for use as anti-infectives (Col 16, Lines 46-50). **MA** teaches that the impurity is selected from radioactive materials (Col 2, Lines 1-5), since they are useful for a variety of medical purposes, being particularly suitable for treatment of cancer (Abstract).

It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **VI, WU** and **YA** with

- the method of **AB** that specified that the impurity was selected from biologic material, since it would be possible to seed and grow fibroblasts enabling production of an extracellular matrix similar to that of natural connective tissue;

- method of **JO** that specified that the impurity was selected from bone, since that would provide an osteoconductive matrix providing a scaffold for bone ingrowth and osteoinductive factors providing chemical agents that induce bone regeneration and repair;

- method of **BO** that specified that the impurity was selected from crushed bone, since this material has the ability to simulate new bone formation;

- method of **WA** that specified that the impurity was selected from co-factors, as the cofactors activate the enzyme impregnated in the lumen, within the biological system;

- method of **TA** that specified that the impurity was selected from biological cells, as biological cells are completely degradable into biomass without having toxic effect on the microbes;

- method of **SL** that specified that the impurity was selected from bio-active materials, since that would describe the manufacturing method for materials including bio-active materials which would be useful to reducing friction, providing a therapeutic for local or blood delivery etc;

- method of **HE** that specified that the impurity was selected from medications, since medications could be dispensed for the dressings;

- method of **PH** that specified that the impurity was selected from antibiotics, since antibiotics could be introduced into the host for use as anti-infectives; and

- method of **MA** that specified that the impurity was selected from radioactive materials, since they are useful for a variety of medical purposes, being particularly suitable for treatment of cancer.

It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of **VI, WU** and **YA,** so the impurity is selected from the group consisting of: biologic materials, bone, crushed bone, co-factors, biological cells, bio-active material, medications, antibiotics, and radioactive materials, to achieve the desired benefits.

18.2 As per Claims 44 and 45, these are rejected based on the same reasoning as Claim 43, supra. Claims 44 and 45 are method claims reciting the same limitation as Claim 43, as taught throughout by **VI, WU, YA, AB, JO, BO, WA, TA, SL, HE, PH** and **MA.**

Arguments

19.1 As per the applicant's argument that "Claims 1, 25 and 41 have been amended to describe methods in which an impurity is introduced into an object while the object is manufactured, wherein the amount of introduced impurity is variable for the respective volume increments of the object; during the element by element manufacturing of an object, one amount of impurity may be introduced at the surface of the object while another amount of impurity may be introduced beneath the surface of the object; the proposed combination of St. Ville and Wu et al. does not teach or suggest introducing an impurity as claimed", the examiner has used a new reference Yamazaki (**YA**). **YA** teaches introducing an impurity into the object while the object is manufactured, wherein an amount of the introduced impurity is variable for the respective volume increments of the object (Col 2, Lines 35-46; Col 2, Lines 15-33)

Conclusion

20. The prior art made of record and not relied upon is considered pertinent to the applicant's disclosure.

The following patents are cited to further show the state of the art with respect to manufacturing composite materials and introducing impurities during manufacturing process.

1. Barker et al., "Electrolytes having improved low temperature performance", US 2002/0009651 A1, January 2002.

2. Yamanaka et al., "Electrooptic device, driving substrate for electrooptic device ...", U.S. Patent 6,372,558, April 2002.

ACTION IS FINAL – NECESSIATED BY AMENDMENT

21. Applicant's amendments necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

22. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Kandasamy Thangavelu whose telephone number is 703-305-0043. The examiner can normally be reached on Monday through Friday from 8:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Teska, can be reached on (703) 305-9704. The fax phone number for the organization where this application or proceeding is assigned is 703-746-73210.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-305-9600.

K. Thangavelu
Art Unit 2123
September 15, 2003

SAMUEL BRODA, ESQ.
PRIMARY EXAMINER